NATIONAL TUBERCULOSIS CONTROL PROGRAMME

OCTOBER 1997

TECHNICAL GUIDELINES FOR TUBERCULOSIS CONTROL IN CONVENTIONAL CHEMOTHERAPY AREAS

CENTRAL TB DIVISION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI 110 011

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Introduction

The aim of the fight against tuberculosis is

- *for individual patients*: to cure disease, to quickly restore and preserve work-capacity, to allow them to be within the family and community, and thereby maintain their socioeconomic status.

- *for the community*: to reduce the risk of tuberculosis infection through early case-finding and by appropriate management and cure.

The fight against tuberculosis is best conducted within the setting of a National Tuberculosis Programme (NTP) integrated with the general health services. The first priority of NTP is the treatment, appropriate management and cure of tuberculosis patients, especially sputum-positive cases detected through direct microscopy. Smear-negative patients should also be given chemotherapy if active tuberculosis is diagnosed. The treatment of smear-positive cases is a priority as it is the only way to break the chain of transmission of the disease.

Case-finding through sputum smear microscopy and treatment of tuberculosis can be carried out at the general health facilities by paramedical workers, if they are properly trained and regularly supervised. Case-finding and cure of infectious cases of tuberculosis will lead to effective control of the disease. Case-finding followed by proper treatment reduces suffering, disability and death from tuberculosis.

What is Tuberculosis? 1

1.1 Cause of the disease

Infectious agent

The aetiological agent is *Mycobacterium tuberculosis* primarily from humans. Other mycobacteria occasionally produce disease clinically indistinguishable from tuberculosis (TB), which are identifiable only through culture.

Disease progression

Transmission is mainly through air by inhalation of droplet nuclei. The initial infection usually goes unnoticed. Tuberculin sensitivity appears within a few weeks of infection. Initial lesions commonly heal leaving no residual changes except occasional pulmonary or tracheobronchial lymph node calcifications (primary complex). Approximately 95% of those initially infected enter this latent phase from which there is life-long risk of reactivation. In approximately 5%, the initial infection may progress directly to pulmonary TB or by lympho-haematogenous dissemination of bacilli, to pulmonary, miliary, meningeal or other extra-pulmonary involvement. The initial infection has a serious outcome more frequently in infants, adolescents and young adults.

Extra-pulmonary TB is much less common than pulmonary TB. It may affect any organ or tissue and includes TB meningitis, miliary TB, involvement of lymph nodes, pleura, bones, joints, intestines, pericardium, kidney, skin, etc.

Progressive pulmonary TB arises from endogenous reactivation of latent foci which remained dormant since the initial infection, or exogenous reinfection which, if untreated, leads to death within 2–3 years in at least half the patients.

1.2 Occurrence

The disease occurs worldwide, with a higher incidence in developing countries. In India, the estimated prevalence of sputum-positive patients is 0.4% (3.5 million cases). Under the NTP, approximately 1.5 million total cases are detected and put on treatment every year. An estimated 0.5 million deaths from TB occur every year. A person infected with

M. tuberculosis who is not infected with HIV has approximately a 10% lifetime risk of developing tuberculosis disease; 50–80% of this risk is in the first two years after infection with *M. tuberculosis* in these HIV-negative patients. Persons infected with *M. tuberculosis* who are also HIV infected have at least a 50% lifetime risk of developing tuberculosis, with an annual risk of developing disease of approximately 7–10%, which is many times higher than that of HIV-negative patients. In developed countries, the mortality and morbidity from TB was declining over the last few decades but since the 1980s morbidity has increased especially in areas or population groups with high prevalence of HIV.

The prevalence of infection detected by tuberculin testing increases with age and in India it is more than 40% in adults.

1.3 Transmission—Route of infection—Forms of tuberculosis

Tuberculosis is most commonly transmitted by inhalation of infected droplet nuclei which are discharged in the air when a patient with untreated sputum smear-positive TB coughs or sneezes. If the bacillus succeeds in infecting a person, active disease results in only about 5–10% of those who had primary infection.

Infection occurs almost exclusively through the respiratory route. Tuberculosis then spreads from the primary lung lesion to other parts of the body via the blood stream, lymphatic and bronchial systems and may thus affect any organ.

- *Pulmonary TB*: Tuberculosis affects the lungs in more than 80% of cases. Pulmonary TB which is sputum smear-positive is highly infectious and should receive topmost priority for treatment.

  Cases which are only sputum culture-positive but smear-negative, are much less infectious than those which are smear-positive.

- *Extra-pulmonary TB* can affect any part of the body, such as the lymph nodes, bones and joints, the genito-urinary tract, the nervous system (meningitis), intestines, etc. Diagnosis is often difficult and it should be made by a physician. Patients with extra-pulmonary TB (without concomitant pulmonary TB) hardly ever spread the disease to others.

- *Tuberculosis in children*: Sputum usually cannot be obtained from children and, in any case, it is often negative even on culture. The diagnosis of TB in children

therefore rests largely on clinical history, contact history, X-ray examination and tuberculin testing. The decision whether or not to treat the child for TB should be made by a physician.

Generally, any tuberculin-positive child under 5 years of age who is a contact of an adult sputum-positive case and has signs or symptoms suggestive of TB should be regarded as having active TB and given a full course of treatment, regardless of whether or not he has been vaccinated with BCG.

1.4 When should tuberculosis be suspected?

The most common symptoms of pulmonary TB are persistent cough (usually with sputum, sometimes blood-stained), fever and chest pain for 3 weeks or more. Constitutional symptoms like lethargy, lassitude, loss of appetite and weight loss may be associated.

In extra-pulmonary TB, symptoms depend on the organs involved, for example:

- swelling, occasionally with pus discharge when lymph nodes are affected;
- pain and swelling of the joints if these are involved;
- headache, fever, stiffness of the neck and mental confusion when there is tuberculous meningitis.

1.5 Health education

The general public should be taught the importance of reporting at a health facility at the earliest if they have chest symptoms, especially productive cough persisting for 3 weeks or more. Patients with these symptoms should undergo a sputum examination at the nearest health facility. People should be informed of the location and facilities available for managing TB at the community level. Patients should be informed that tuberculosis is curable if all medicines are taken as prescribed, and that treatment must continue even when symptoms are no longer present, until the physician discontinues it.

1.6 A "case" of tuberculosis

A case of pulmonary TB is a patient who is sputum smear-positive for Acid-Fast Bacilli (AFB) or if found sputum smear-negative is considered by a physician to be suffering from

the disease on the basis of clinical and radiological evidence. A case of extra-pulmonary TB is a patient who is considered by a physician to warrant complete treatment based on clinical, histological, or other evidence. All cases of tuberculosis should be registered.

1.7 Classification of tuberculosis cases

Classification of pulmonary cases should be based on 3 sputum smear examinations. Sputum should also be examined for cases of suspected extra-pulmonary TB if pulmonary symptoms are present.

Pulmonary tuberculosis, smear-positive
TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB,

Or: Tuberculosis in a patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating Medical Officer,

Or: Tuberculosis in a patient with one sputum specimen positive for AFB and culture positive for *M. tuberculosis*.

Pulmonary tuberculosis, smear-negative
TB in a patient with symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by a Medical Officer, followed by a decision to treat the patient with a full course of anti-tuberculosis therapy,

Or: Diagnosis based on positive culture but negative AFB sputum examinations.

Extra-pulmonary tuberculosis
TB of organs other than the lungs, such as the pleura (TB pleurisy), peripheral lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis, tuberculoma of the brain, etc.

Diagnosis should be based on one culture-positive specimen from an extra-pulmonary site, or histological evidence, or strong clinical evidence consistent with active extra-pulmonary TB followed by a Medical Officer's decision to treat the patient with a full course of anti-tuberculosis therapy.

Pleurisy is classified as extra-pulmonary TB.

A patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary TB.

Case categories

New case
A patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month.

Relapse
A patient declared cured of TB by a physician, but who reports back to the health service and is found to be bacteriologically positive.

Transferred in
A patient who has been received into a District, after starting treatment in another unit where he has been recorded.

Treatment after default
A patient who received anti-tuberculosis treatment for one month or more from any source and who returns to treatment after having defaulted, i.e. not taken anti-TB drugs consecutively for two months or more.

Failure case
Smear-positive patient who is smear-positive at 6 months or more after starting treatment. Failure also includes a patient who was initially smear-negative but who becomes smear-positive during treatment.

Chronic case
A patient who remains smear-positive after completing the full duration of treatment.

"Other" case
Patients who do not fit into the above-mentioned categories. Reasons for putting a patient in this category must be specified.

A comparison of the previously published definitions and regimens of the National Tuberculosis Programme with the above definitions is presented in Annexure 1.

Diagnosis of Tuberculosis 2

2.1 Case-finding methods

- Examination of sputum of patients with symptoms suggestive of TB (productive cough for 3 weeks or more with or without haemoptysis, fever, chest pain, weight loss or night sweats), who present on their own initiative at health facilities;

- Promotion of awareness in the community, the medical profession and all medical staff regarding respiratory symptoms, notably persistent productive cough for 3 weeks or more, and the need to obtain and examine sputum specimens for the diagnosis of TB;

- Examination of household contacts (especially children below 5 years) of smear-positive TB patients; and

- Examination of the sputum of a patient who, for any reason, has had an X-ray of the chest which has shown abnormality consistent with active TB.

2.2 Diagnosis

Microscopic examination of sputum is, as a rule, the only way by which the diagnosis of pulmonary TB can be confirmed.

Whenever TB is suspected, at least 3 specimens of sputum should be collected and examined by microscopy. If possible, they should be obtained over 2 days.

- *First visit to the microscopy centre*: A spot specimen is collected; this is a specimen obtained on the spot after coughing and clearing the throat, under supervision of a staff member. The patient is then given a sputum container for collection of an early morning specimen and instructed to come with this sputum sample on the next working day.

- *Second visit to the microscopy centre*: The early morning collection of sputum specimen (second specimen) brought by the patient is received and a further spot specimen is collected (third specimen).

- All specimens should be examined in the nearest microscopy laboratory, as a rule, by the Ziehl–Neelsen method (See Laboratory Manual).

If the first spot specimen is positive by microscopy and the patient does not return for the second sputum test, an immediate search must be made to find the patient to prevent dissemination of infection in the community. In the interest of the patient second and third specimens of sputum must be collected and examined. To facilitate this it is important to note down the complete address of all symptomatic patients who are being evaluated.

If required, a course of symptomatic treatment or antibiotics suitable for non-tuberculous infection (but not streptomycin or rifampicin) may be given while awaiting the laboratory smear reports on the specimens. If a smear-negative patient fails to respond to this treatment and remains ill, the patient should be referred for further investigation (clinical and radiological). The extra-pulmonary cases with productive cough should also be examined by sputum smear to exclude pulmonary TB.

The diagnosis of TB by X-ray is unreliable, because other chest diseases can resemble TB on an X-ray, and because pulmonary TB may show various types of radiographic abnormalities. It must be stressed that the determination of clinical activity of TB by X-ray is totally unreliable. Moreover, the cost of X-ray examination is relatively high in relation to case-finding by smear microscopy. Consequently, the diagnosis of TB in adults must, as a rule, be confirmed by smear examination.

X-ray examination can undoubtedly be helpful in clinical work-up when investigating patients with symptoms suggestive of TB who have negative AFB smears, contacts of infectious cases, and in patients suffering from miliary or extra-pulmonary TB. In patients with chest symptoms with negative smears for AFB, a course of antibiotics for one to two weeks should be tried before taking a chest X-ray.

The tuberculin test has limited value in clinical work, especially in countries like India which have a high prevalence of TB Infection. A "positive" tuberculin test (10 mm or more induration after 48 hours with 1 TU of PPD) is merely an indication of infection and is infrequently followed by disease. A "negative" tuberculin test does not necessarily exclude active TB. Moreover, a "positive" tuberculin test may be due to infection with

mycobacteria other than *M. tuberculosis* or due to BCG vaccination. However, the tuberculin test is important in clinical work with children in whom a positive test is more likely to reflect recent infection with TB and indicates a much higher risk of developing disease.

Diagnosis in children is made by a physician on the basis of clinical symptoms, a positive Mantoux tuberculin skin test, chest X-ray and history of contact with a case of TB.

Contacts of smear-positive index cases

Any person who has productive cough and is in contact with a smear-positive index case should have 3 sputum examinations as soon as possible. If the results are negative and symptoms persist after treatment with broad-spectrum antibiotics the patient should have a chest X-ray and undergo examination by a Medical Officer. If the results of this evaluation are doubtful, he should be followed up 3 months later.

Children who cannot produce sputum should be examined with other recommended investigations like chest X-ray and tuberculin testing.

Children under five years: A contact with a positive Mantoux test (10 mm or more) is to be treated as a case if he is symptomatic, regardless of whether or not he has been given BCG vaccination in the past. If there are no signs or symptoms he should report if they appear.

Infants: If the mother or another household member is smear-positive then chemoprophylaxis should be given for 3 months. After this do a Mantoux test. If this is negative, stop chemoprophylaxis and give BCG. If the Mantoux test is positive continue chemoprophylaxis for a total duration of 6 months.

Chemoprophylaxis and evaluation of child contacts of sputum-positive cases should be done in consultation with a paediatrician.

2.3 Complications of tuberculosis

(a) Pulmonary tuberculosis

Haemoptysis (coughing up of blood). In severe cases the patients should be advised rest, sedatives and antitussives and referred to the nearest hospital.

Spontaneous pneumothorax (collapse of the lung due to damage caused by TB). The patient must be referred to the nearest hospital for further management.

Pleural effusion. If the amount of fluid is not very large, the clinical condition will improve with chemotherapy alone. If there is too much fluid in the thorax, aspiration may be necessary for relief of symptoms and the patient should be referred to hospital.

Cardio-pulmonary insufficiency (combined heart and lung disease—cor pulmonale). A Medical Officer should be consulted regarding therapy.

Bronchiectasis, fibrosis of the lungs. These are sequelae of extensive tuberculous disease and only symptomatic therapy is usually available.

(b) Extra-pulmonary tuberculosis

Complications depend on the organs involved. A Medical Officer must be consulted.

Tuberculosis Laboratory Service

3

3.1 Aims of the laboratory service

The aims of the laboratory service are: (i) the diagnosis of cases, and (ii) monitoring of treatment. (A practical description of all procedures related to sputum examination by direct microscopy is given in the Laboratory Manual.)

The TB laboratory service consists of a network of laboratories throughout the country which carry out, as part of their work, microscopic examination of sputum smears stained by the Ziehl–Neelsen method, and also includes Reference Laboratories for Tuberculosis at the State and Central levels.

The Reference Laboratory of Tuberculosis should be capable of training and supervising the staff of the network of microscopy centres. It should provide quality control services for smear microscopy. Some reference laboratories should have facilities for culture and sensitivity tests. Culture and sensitivity tests are not done as a matter of routine for diagnosis and is primarily of value for drug sensitivity studies in cases of treatment failures and for research purposes.

Efficient peripheral laboratories play a crucial role in the success of the case-finding programme based on the detection of smear-positive cases. Microscopy centres for examination of sputum for detecting tubercle bacilli are usually located in hospitals and health centres.

3.2 Smear examination

For diagnosis 3 sputum samples should be tested. The smear-positive slides may either be broken, disinfected and disposed of like any other glass scrap. All negative slides after laboratory cross-check may be washed thoroughly and reused, but not for TB work. For follow-up of sputum smear-positive cases, two sputum samples should be tested each time at the end of the intensive phase (2 months), at six months, and at the end of treatment.

3.3 Supervision

The Medical Officer in charge and other staff supervising the laboratory services should be appropriately trained so that they have adequate knowledge of the techniques of smear examination.

3.4 Disposal of contaminated material

The infected materials and sputum containers may be disposed of as per instructions given in the Laboratory Manual.

General Aspects of Chemotherapy

4

The primary objective of chemotherapy is to cure newly detected smear-positive cases;

The main requirements for adequate chemotherapy are:

- an appropriate combination of anti-tuberculosis drugs,
- taken regularly by the patient,
- for the prescribed period of time.

Drugs should be available to every registered TB case.

4.1 Drug resistance

Every patient with TB has millions of individual tubercle bacilli. Naturally occurring mutants resistant to one anti-tuberculosis drug exist in very small numbers whereas those resistant to multiple drugs do not exist, for all practical purposes.

Inappropriate anti-tuberculosis treatment or irregularity of medication can cause a patient with drug-susceptible TB to develop drug-resistant TB. This is called acquired drug resistance. To prevent this, it is essential that the correct drugs be given in the correct manner for the prescribed period.

When a patient who has a drug-resistant strain of TB infects another person, the tubercle bacilli which spread to the newly infected person are resistant to the same drug(s) as those of the source patient, even though the new patient has never taken these drugs in the past. This is called primary drug resistance.

Patients who have taken anti-tuberculosis drugs previously are much more likely to develop drug resistance as compared to new patients.

4.2 Regularity of chemotherapy

With few exceptions, the regimens under Section 5 will cure newly diagnosed cases of TB, provided that:

- the drugs are taken for the required period;
- they are taken regularly as prescribed;
- the patient on entry is not in a critical condition; and
- the bacilli are not resistant to the drugs administered.

4.3 Duration of chemotherapy

The duration of chemotherapy is 12 months. The patient should stop drugs ONLY on advice of the treating physician and not before.

Chemotherapy should be temporarily interrupted or stopped only if severe drug intolerance or toxicity develops.

4.4 Procedures during treatment

Sputum microscopy is much more informative than radiology in following the progress of chemotherapy. The Erythrocyte Sedimentation Rate (ESR) is unreliable and has no role in diagnosing and/or evaluating the progress or results of treatment. For follow-up of sputum smear-positive cases, two sputum samples should be tested each time at the end of the intensive phase (2 months), at six months, and at the end of treatment.

As regards administration of streptomycin injection at the peripheral level, the policy will be to entrust this responsibility to the Auxillary Nurse Midwife (ANM) at the sub-centre level or any registered doctor at a place agreed to by the patient. If this is not possible the patient has to come to the PHC/CHC and may even be hospitalized for the initial intensive phase during which streptomycin injection is to be given. **Strict sterilization of syringes and needles *must* be ensured.**

4.5 Follow-up

No follow-up is required for a patient who has completed treatment and has been declared cured. He should be advised to report only if symptoms suggestive of TB recur.

4.6 Defaulter action

Action on absentees during treatment is to be taken by bringing the patient back on treatment through all possible methods including home visits. It is important to take action on defaulters immediately after knowing that the patient has defaulted and missed drug collection. Priority for defaulter retrieval should be given to smear-positive patients, particularly to those who have not been previously treated (new smear-positive patients).

Motivation

The health worker should discuss problems with the patient and find ways of preventing him from defaulting, convince him that cure depends on regular drug intake and convey the same message to relatives so that they can take an interest in ensuring regular drug taking by the patient. The health worker should discuss with the patient where he would prefer to take his treatment. Do not blame the patient; try to understand his or her difficulties and then motivate accordingly. It is best to negotiate a plan for treatment which gives the best chance to achieve cure.

4.7 In-patient versus out-patient treatment

Hospitalization in itself has little or no effect on the outcome of treatment: a patient who takes the drugs will do equally well whether treated in or out of hospital.

In-patient treatment is indicated (often only for a few weeks) for the severely ill, for those with complications of TB (e.g. haemoptysis, spontaneous pneumothorax), or for those with other serious accompanying diseases. **During hospitalization, all drugs must be administered under the direct observation of the health staff.**

4.8 Tuberculosis treatment during pregnancy and breastfeeding

Active TB presents a special problem in women who are pregnant or in mothers who have small children. Pregnant women with active tuberculosis should start or continue their anti-tuberculosis treatment. (Streptomycin should not be given during pregnancy because it crosses the placenta and may cause damage to the fetus.)

Breastfeeding of infants should continue irrespective of the TB status of the mother. If the mother is sputum smear-positive for AFB, the child should be given chemoprophylaxis for 3 months and then vaccinated with BCG if the child is tuberculin-negative. If tuberculin is positive at 3 months, the child should not be given BCG and chemoprophylaxis should

be continued for a total duration of 6 months. If the mother is sputum smear-negative for AFB, the child is vaccinated with BCG and no chemoprophylaxis is necessary.

4.9 Tuberculous meningitis

Tuberculous meningitis is a fatal disease if left untreated. The symptoms may be non-specific. On lumbar puncture, the cerebrospinal fluid (CSF) is under increased pressure, clear or slightly turbid and a fine clot forms like a cobweb if left to stand. Classically, the CSF shows lymphocytosis with high protein and low sugar levels.

Treatment should be started as soon as possible. The regimen described in Section 5 for severely ill patients should be given. When feasible, short-course chemotherapy including rifampicin and pyrazinamide for the first two months should be given.

Drugs and Regimens 5

Do not start treatment for TB until a firm diagnosis has been made. Three sputum smear examinations should have been done before starting chemotherapy. Treatment for a smear-positive case can begin with only two positive smears, a third examination is then not required.

Priority for treatment is given to pulmonary smear-positive cases. Two treatment regimens are recommended:

5.1. Smear-positive pulmonary and seriously ill (pulmonary or extra-pulmonary)cases

Treatment is with 12 months of either isoniazid and ethambutol or isoniazid and thiacetazone, supplemented in the first 2 months with streptomycin.

5.2. Smear-negative pulmonary cases and extra-pulmonary cases

Treatment is with 12 months of either isoniazid and ethambutol or isoniazid and thiacetazone.

Isoniazid and thiacetazone are self-administered daily for 12 months. Thiacetazone should be replaced with ethambutol if the patient has or is at risk for HIV infection, or in case of intolerance or toxicity.

The dosage for adults is one combined tablet of isoniazid 300 mg and thiacetazone 150 mg daily. The dose for ethambutol is 800 mg per day. The dose for injection streptomycin is 0.75 g per day (0.5 g for those over 50 years of age). Daily doses for children are given in the following table.

Dosages for Children

Pretreatment Weight	Number of Tablets		
	Isoniazid 100 mg	Ethambutol 400 mg	Thiacetazone* 50 mg
Up to 10 kg	½ tablet	–	½ tablet
11 to 20 kg	1 tablet	–	1 tablet
21 to 30 kg	2 tablets	1 tablet	2 tablets
30 kg and above	3 tablets	1½ tablets	3 tablets

*Thiacetazone is always combined with isoniazid.

Side-effects of Anti-tuberculosis Drugs

6

Side-effects of anti-tuberculosis drugs are of two types:

- Major side-effects are those which lead to serious health hazards;
- Minor side-effects cause only relatively little discomfort; they often respond to symptomatic or simple treatment but occasionally persist for the entire duration of drug treatment.

6.1 Isoniazid

Hepatitis, a major side-effect, occurs in about 0.5% of cases. If jaundice develops, stop treatment, transfer the patient to a hospital for further management.

Minor side-effects include peripheral neuropathy, pellagra-like syndrome, skin rash, drowsiness and fatigue.

6.2 Isoniazid/Thiacetazone

Hepatitis, a major side-effect, occurs when the two drugs are given in combination or with isoniazid alone.

Cutaneous reactions in patients treated with this medication (due to thiacetazone) may be more serious than with other drugs. Exfoliative dermatitis or Stevens–Johnson syndrome may occur and can be fatal. Stevens–Johnson syndrome is a special type of hypersensitivity reaction characterized by a generalized bullous eruption, sometimes haemorrhagic, involving skin and mucous membranes. When this occurs, **medication should be stopped immediately and thiacetazone should never be given again.** Immediate treatment with corticosteroids is indicated; the patient must be sent without delay for admission to hospital and emergency treatment. Cutaneous reactions to thiacetazone occur more frequently and are more severe in HIV-positive patients. **For this reason thiacetazone should never be given to HIV-positive patients.**

Gastrointestinal (GIT) upsets, such as nausea, vomiting and diarrhoea, are also common. Symptoms usually subside if the daily dose is divided and given half in the morning and half in the evening for a week or so. Sometimes antacids are recommended.

6.3 Ethambutol

Ethambutol may produce impairment of vision—a decrease in visual acuity, blurring and red–green colour blindness. However, ocular toxicity seems to be clearly dose-dependent.

Every patient receiving ethambutol should be warned that if visual symptoms occur, an ocular examination should be undertaken. Impaired vision usually returns to normal within a few weeks after the drug is stopped. **Because of the risk of undetected ocular toxicity, ethambutol should not be given to children below 6 years of age.**

6.4 Streptomycin

The main toxic side-effect of streptomycin is vestibular damage. The risk increases with the dose and age. The dose is reduced to 0.5 g for patients over 50 years of age. Damage to the vestibular system usually occurs in the first 2 months and is manifested by ringing in the ears, giddiness and ataxia. The risk is particularly high in patients with impaired excretory function of the kidneys. The drug must be stopped if the side-effect appears. Streptomycin should not be used in pregnancy.

Hypersensitivity reactions occasionally occur, like sudden onset of fever often accompanied by headache, vomiting and an irritating erythematous rash. Stop treatment (both streptomycin and thiacetazone) and admit the patient to hospital.

Sterilization of syringes and needles for streptomycin injections

1. Health workers must use a separate sterile syringe and a separate sterile needle for every patient for each injection.

2. Needles and syringes should be thoroughly cleaned before sterilizing them. Sterilization by autoclave/hot air oven is preferred wherever feasible. A properly washed needle and syringe wrapped in paper should be kept in hot air oven at 160 °C for one hour. Sterilization in an autoclave is achieved at 115 °C/15 lbs/15 minutes.

3. When using a **steam sterilizer**, remember:

   - Place instruments in the steam arising from boiling water for 15 minutes
   - Do not cover instruments within the steam sterilizer with water
   - Do not use it on an open wood fire. (It might not produce enough heat)
   - In high altitudes sterilize the instruments for a longer period of time

4. Sterilization by **boiling**:

   This method should be used only where there is no alternative. Use a special boiling pan or, if not available, a saucepan. Fill with water. Heat over the stove. Glass syringes should be put in while the water is still cold. Needles and forceps should be put in when the water is boiling. Leave these articles to boil for 20 minutes, counting time after the water has started boiling.

5. Sterile syringes and sterile needles should be kept in a sterile covered container.

6. Use sterile forceps to take sterile instruments out of the sterile covered container.

7. When holding a sterile syringe, touch only the safe parts of the syringe, i.e. outside of the barrel or the top of the plunger.

8. Wash your hands when you come in contact with body fluids or infected material.

Role of BCG Vaccination 7

Effective treatment of infectious patients protects children against all forms of TB and also improves child survival by improving the health of families. The most effective way to prevent TB is to ensure that sputum smear-positive patients are cured. To protect contacts of sputum smear-positive cases, examination should be carried out and treatment given as described in Section 5.

BCG is an attenuated strain of bovine tubercle bacilli. It is given by intradermal injection to non-infected children to protect them from developing severe forms of the disease, e.g. tuberculous meningitis and miliary tuberculosis. BCG vaccination does not decrease the spread of TB.

BCG vaccination is given to infants as early in life as possible. It is included in the Expanded Programme on Immunization (EPI). The NTP follows the recommendations of the EPI on the vaccination. The dose of the vaccine is 0.1 ml.

Complications of vaccination are uncommon, but include:

- subcutaneous abscess at the site of injection
- ulceration at the site of injection
- swelling with or without ulceration of the regional lymph nodes
- systemic complications (very rare)

General guidelines on treatment of complications:

- subcutaneous abscess and ulceration at the site of injection may only require simple analgesics for pain relief and cleaning of the ulcer. A large abscess can be aspirated with a syringe and needle.
- mild swelling of axillary lymph nodes on the vaccinated side usually requires no treatment.

Management of Patients with HIV Infection and Tuberculosis 8

8.1 Introduction

Infection with the Human Immunodeficiency Virus (HIV) is the cause of AIDS. HIV infection destroys the immune system, especially the lymphocytes. As a result, patients with HIV/AIDS are much more susceptible to many infections, including TB. In some studies, more than half of all AIDS patients in India had TB.

Despite this increased susceptibility to TB, patients with HIV/AIDS can be cured of TB. Such treatment not only prolongs the life of patients with AIDS, but also stops the spread of TB, both to other HIV-infected persons and to the general public.

HIV infection is increasing in India. Although the exact size of the HIV epidemic in our country is not known, it is certain that with increasing cases of AIDS, there will be more patients with both AIDS and TB, increasing the need for anti-tuberculosis treatment. HIV-infected people who develop TB further spread the disease in their community.

The HIV epidemic heightens the need to ensure identification and cure of smear-positive TB patients. The principles and priorities of TB control are the same for tuberculosis patients with and without HIV infection.

8.2 Diagnosis of TB in patients with HIV

The diagnosis of TB in patients with HIV is more difficult than in those without HIV for three reasons:

- HIV-infected patients are more likely to have negative sputum smears, especially in the later stages of AIDS. HIV therefore reduces the proportion of TB patients who are sputum smear-positive.

- X-ray abnormalities, which are not specific for TB in HIV-negative patients, are even more non-specific in HIV-infected patients. In HIV-infected patients, TB may

be present with only minor abnormalities on chest X-ray or with abnormalities which do not look like "classic" TB. This may result in under-diagnosis of TB by X-ray.

- Patients infected with HIV have frequent pulmonary infections. Each time such an infection occurs, the patient must be evaluated for TB. Because of the frequent pulmonary infections in HIV infected patients, there is a strong possibility of overdiagnosis of tuberculosis in such cases.

When patients with HIV have a pulmonary infection, they should be evaluated for TB with 3 sputum examinations for AFB. If sputum smear-negative, they should receive treatment for bacterial pneumonia, which is also common in such patients. If routine antibiotics do not relieve the symptoms, then after appropriate diagnostic studies (chest X-ray, sputum culture for mycobacteria, if available), the patient can be treated for TB. Clinical diagnosis based on X-ray examination in sputum smear-negative patients should only be made by an experienced Medical Officer.

In patients with HIV and TB, extra-pulmonary forms of TB are more common. These include lymphatic disease, pleural effusion, pericardial disease, miliary TB and tuberculous meningitis.

8.3 Treatment of TB in HIV-infected patients

Treatment of HIV-infected TB patients is identical to that of HIV-negative TB patients, with the exception of the use of thiacetazone. Because of the risk of fatal skin reactions to thiacetazone this drug should never be used in HIV-infected patients. Streptomycin and other injections remain useful provided that sterilization of needles and syringes can be ensured.

Because patients with HIV have weaker immune systems, it is particularly important that treatment recommendations be fully adhered to. Patients with HIV infection also appear more susceptible to developing drug resistant strains of the disease.

8.4 Management of HIV and TB infections

Management of HIV and TB infections should emphasize:

- promotion of early identification of AIDS patients with suspected TB, with improved referral services for diagnosis, initiation and completion of treatment;

- development of educational materials emphasizing the modes of transmission of HIV, the risk of developing TB in AIDS cases as well as the need for regular and complete treatment. Emphasis needs to be placed on the importance of screening households/contacts of AIDS patients with TB. Educational material on the risk of AIDS transmission through the use of syringes/needles is also required for TB service providers;

- involving NGOs working locally so that they take up activities of both TB and AIDS programmes; and

- coordination by means of regular interaction, joint coordination committees, etc.

8.5 Training needs of health care workers in relation to HIV and TB

Health workers who care for patients with HIV/AIDS should, at the minimum, be trained to:

- recognize symptoms of TB;

- know the importance of diagnosing TB by sputum microscopy;

- be aware of the increased possibility that sputum microscopy will be negative in HIV-infected patients with TB, and the need for further evaluation of these patients;

- know that HIV-infected patients have increased susceptibility to TB. They need to promptly diagnose TB in order to prevent HIV/TB patients from infecting others in treatment or residential facilities for HIV-infected persons;

- know the modes of spread of HIV and be able to counsel patients and family members on HIV/AIDS.

Note: It is extremely important to ensure that all patients with TB who are in a hospital or residential facility for HIV-infected persons have an uninterrupted drug supply and take every dose of their anti-TB medicine. If these patients do not take anti-tuberculosis medications as prescribed, they may spread the disease rapidly to other HIV-infected persons as well as to others.

Health workers who care for TB patients should be aware of the following in relation to HIV/AIDS:

- difficulty of diagnosing HIV/TB patients;
- increased frequency of smear-negative and extra-pulmonary TB in HIV-positive patients;
- effectiveness of treatment, even if TB patients are HIV-infected;
- importance of avoiding thiacetazone in HIV-infected patients and in high-risk groups and high-risk areas;
- strict adherence to the treatment protocol;
- need to be non-judgemental in caring for patients with HIV infection;
- importance of correct sterilization and disposal of needles used for streptomycin injections;
- need to promote the use of condoms to reduce spread of HIV; and
- location and details of services available for HIV-infected patients in their area.

Note: TB control staff need to coordinate closely with other services to provide support and care for HIV-positive patients.

8.6 Areas for collaboration between TB and AIDS programmes

There are many potential areas for collaboration between TB and AIDS programmes. Examples include:

- TB programmes can provide training to staff caring for HIV/AIDS patients, and vice versa;
- TB diagnosis and treatment of HIV-infected persons can be provided or supported by the TB programme;

- HIV counselling and testing centres can provide TB screening and education;
- care of HIV-related illnesses of TB/HIV patients can be provided by the HIV/AIDS programme.
- TB and HIV programmes can work individually and jointly to advocate more effective services for patients with HIV and TB.

Recording and Reporting 9

Accurate keeping of records on all individual patients, and periodic reporting with statistics on patients and activities, together with explanatory remarks is essential for planning, forecasting, procuring and distributing drugs, laboratory reagents, sputum containers, manpower requirement, as well as evaluating control measures applied in the TB programme.

The following recording and reporting forms are used:

Records

- Tuberculosis Register: kept at district level in States or chest clinic level in metropolitan cities.
- Treatment Card for each patient under treatment: kept in all peripheral health units.
- Patient's Identity Card: kept by the patient.
- Transfer Form: kept at the peripheral health unit administering treatment.
- Tuberculosis Laboratory Register: kept at laboratories carrying out sputum examination for tubercle bacilli.
- Laboratory Form for Sputum Examination: kept in all peripheral health units.

Reports

- Quarterly Report on Case-Finding: filled at district/chest clinic level.
- Quarterly Report on Smear Conversion: filled at district/chest clinic level.
- Quarterly Report on Results of Chemotherapy of Tuberculosis Patients Registered 15–18 Months Earlier: filled at district/chest clinic level by a health worker responsible for the NTP and sent to the district/city headquarter level.
- Quarterly Report on Programme Management.

Detailed instructions for filling up formats are given in Annexure II, and formats are given in Annexure III.

Evaluation 10

An in built evaluation system is an integral component of the NTP. It is mandatory to collect information regularly on detection of smear-positive cases (new cases must be separated from other smear-positive cases including relapses, failures, defaulters returning to treatment and chronic cases) and on the results of chemotherapy.

10.1 Evaluation of case-finding

Diagnostic practices can be evaluated by determining the proportion of patients examined out of those attending the health facility, and the proportion of smear-positive cases among all pulmonary cases diagnosed. In general, it is expected that about 2–3% of adult outpatients will be chest symptomatics, and that about 10% of chest symptomatics examined will be sputum-positive is much less than half, either smear examinations are being done poorly, or there is overdiagnosis of smear-negative TB, or both.

10.2 Evaluation of treatment

"Quarterly Report on Results of Chemotherapy of Smear-positive Cases of Pulmonary Tuberculosis". Cohort analysis is the most important part of evaluation of the programme. The results of chemotherapy should be reported as discussed above.

The priority in tuberculosis control is to assure that smear-positive patients complete treatment and are cured. Case-finding activities are of secondary importance. In fact, unless completion/cure rates are high, case-finding is counterproductive, because large numbers of patients are placed on treatment and not cured, resulting in development and spread of drug-resistant tuberculosis.

Quarterly reports on cases are made so as to permit cohort analysis. (A cohort refers to a group of individuals with common characteristics; in this case the cohort includes all patients registered in a district/ward during a quarter.) The TB Register is used to prepare these reports. Accurate and timely reports can only be produced if the TB Register is kept up to date.

The most important report is the Quarterly Report on the Results of Treatment of Pulmonary Tuberculosis Patients Registered 15–18 Months Earlier.

Annexures

Annexure I

Comparison of definitions with previous publication of National Tuberculosis Programme

NTP Regimen Code	NTP description	Type of patient using revised definitions
R_1 2 HSE 10 HE	a. New smear-positive cases	Smear-negative pulmonary, seriously ill, including new and retreatment patients
	b. Smear-negative patients with extensive radiological evidence of disease/cavity/ toxaemia	Smear-positive, new
	c Extra-pulmonary patients in general (e.g. tuberculous lymphadenitis)	Extra-pulmonary, new or retreatment
	d. Cases, sputum-positive after treatment completion, who are unable to attend DTC or other specialized centres on referral for further treatment	Failure cases
R_2 12 HE	a. Smear-negative patients with X-ray evidence of tuberculosis	Smear-negative pulmonary, including new and retreatment patients
	b. Lost patients, smear-negative on reporting back, irrespective of previous history of treatment	Smear-negative, return after default
	c. Highly irregular patients	Return after default

Recording, Reporting and Evaluation of Case-finding and Treatment Results

The number of documents used in the programme is limited. The recording and reporting materials to be used are:

1. Recording

The following records are to be used in the NTP.

1.1 Treatment Card

The treatment card is filled as soon as a diagnosis of TB is made. It is kept at the health institution where the patient receives treatment (at the TB clinic, district hospital, CHC, PHC, Health post, etc.). The TB coordinator/supervisor at the health institution transfers the relevant data, particularly the results of bacteriological examinations, from the treatment card to the Tuberculosis Register kept at the district/chest clinic level.

1.2 Tuberculosis Identity Card

This card is filled as soon as the diagnosis of TB is made and is kept by the patient. The most important part of this card contains information on the date of starting treatment, regimen used, appointment dates for collection of drugs and for follow-up examination.

1.3 Tuberculosis Register

This register is kept at the District Tuberculosis Centre and contains information on all TB patients started on treatment.

1.4 Laboratory Register

This register is kept at all TB microscopy centres. The most important information is contained in the columns "Reason for Examination" and "Results". The laboratory technician should carefully tick whether the sputum was collected for diagnosis (chest symptomatics) or for follow-up during treatment. Three sputum specimens are required for diagnosis and two follow-up. For follow-up, the patient's Tuberculosis No. (from the tuberculosis register) must be written in the column provided.

1.5 Laboratory Form for Sputum Examination

It is essential to indicate in the form whether the sputum is sent for diagnosis or follow-up. The detailed address of all patients whose sputum is examined for diagnosis must be given so that patients who are smear-positive and do not return to the health institution can be traced. This form is kept at all health institutions (peripheral, intermediate, central). The tuberculosis No. of all patients whose sputum is examined for follow-up must be written in the space provided.

1.6 Tuberculosis Culture/Sensitivity Form

Request for culture/sensitivity tests will be sent to the central laboratory by the District Tuberculosis Officer.

1.7 Tuberculosis Transfer Form

This form is to be used when transferring patients from one area to another. It must be filled in triplicate and one given to the patient (to hand over at the next health institution), one sent to the health institution directly and the other retained for records. The receiving health institution will fill the bottom half of the form and return it to the transferring institution, as soon as the patient is registered.

2. Reporting

All District TB Officers must submit reports on case-finding, smear conversion, results of treatment and programme management. The forms to be used are:

- *Quarterly Report on New and Retreatment Cases.* This pertains to the patients registered during a quarter and gives case-finding data and the relationship between new sputum-positive and new sputum-negative cases, as well as treatment regimens given.

- *Quarterly Report on Smear Conversion.* This report gives the proportion of smear-positive cases of the cohort registered in the previous quarter who became smear-negative at 2 and 3 months of treatment.

- *Quarterly Report on the Results of Treatment of Tuberculosis Patients Registered 15–18 Months Earlier.* This report shows the treatment outcomes of all cases registered.

- *Quarterly Report on Programme Management.* This deals with the various aspects of programme management, particularly supply of drugs and equipment.

Four copies of these forms are to be completed by each DTO, who will send one to the State HQ, one to the Central TB Division, one to NTI and retain the fourth copy for records.

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Form for Sputum Examination

Name of Health Centre: _____ Date: _____

Name of patient: _____ Age: _____ Sex: M ❑ F ❑

Complete address: _____

_____

Patient's TB No.*: _____

Disease classification: ❑ Pulmonary

❑ Extra-pulmonary Site: _____

Reason for examination: ❑ Diagnosis

❑ Follow-up of chemotherapy*

Specimen Identification No.: _____ Date of sputum collection: _____

Specimen collector's signature _____

*Be sure to enter the TB No. for follow-up of patients on chemotherapy.

RESULTS (To be completed in the laboratory)

Lab Serial No: _____

(a) Visual appearance of sputum

	Mucopurulent	Blood-stained	Saliva
Specimen 1	❑	❑	❑
Specimen 2	❑	❑	❑
Specimen 3	❑	❑	❑

(b) Microscopy

Date	Specimen	Results*	Positive (grading)			
			3+	2+	1+	Scanty
	1					
	2					
	3					

* Write negative or positive

Date: _____ Examined by (signature): _____

The completed form (with results) should be sent to the Health Centre to record the results on the Treatment Card.

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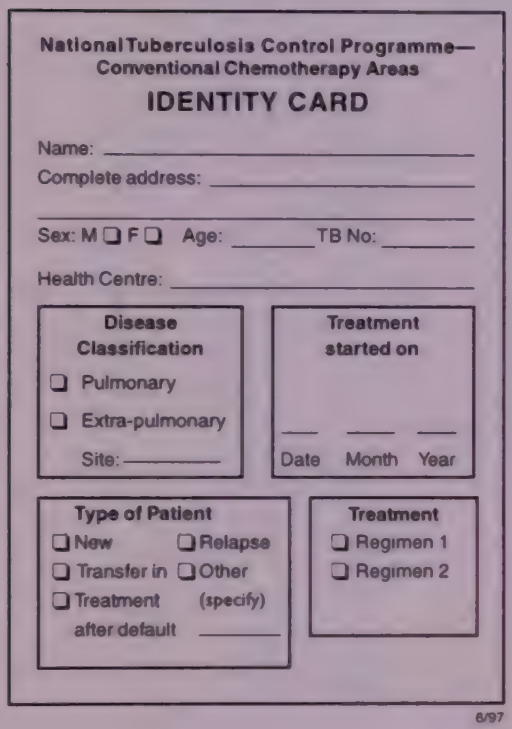
IDENTITY CARD (front)

IDENTITY CARD (back)



National Tuberculosis Control Programme—
Conventional Chemotherapy Areas

IDENTITY CARD

Name: _____

Complete address: _____

_____

Sex: M ❑ F ❑ Age: _____ TB No: _____

Health Centre: _____

Disease Classification

❑ Pulmonary

❑ Extra-pulmonary

Site: _____

Treatment started on

___ ___ ___

Date Month Year

Type of Patient

❑ New ❑ Relapse

❑ Transfer in ❑ Other

❑ Treatment after default (specify) _____

Treatment

❑ Regimen 1

❑ Regimen 2

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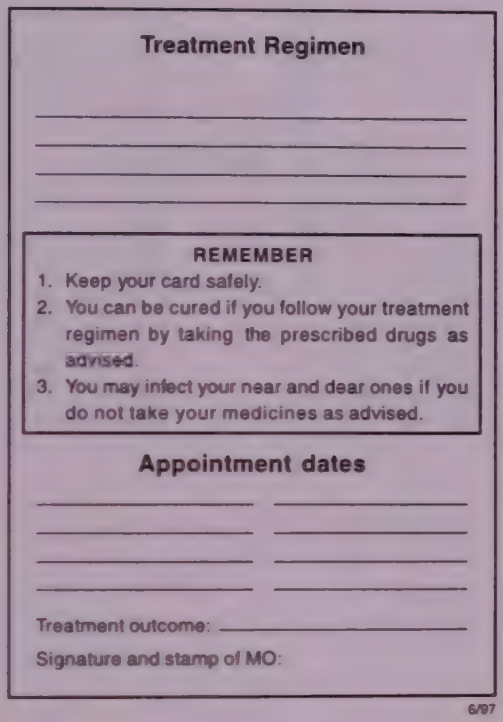

Treatment Regimen

_____

_____

_____

_____

REMEMBER

1. Keep your card safely.
2. You can be cured if you follow your treatment regimen by taking the prescribed drugs as advised.
3. You may infect your near and dear ones if you do not take your medicines as advised.

Appointment dates

_____ _____

_____ _____

_____ _____

_____ _____

Treatment outcome: _____

Signature and stamp of MO:

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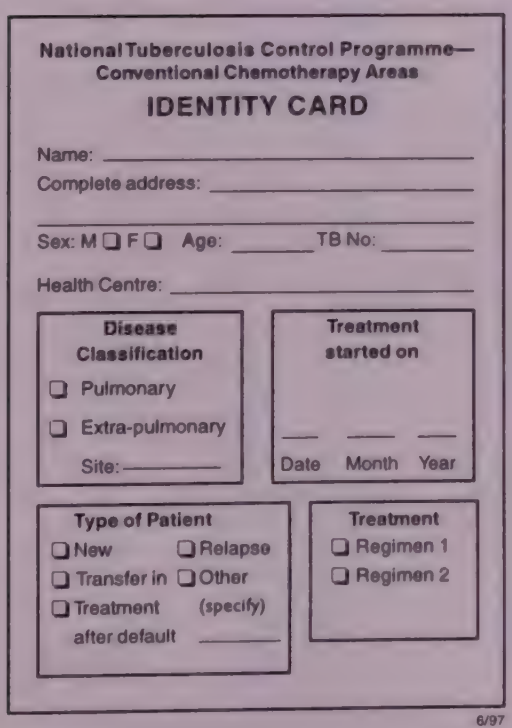

National Tuberculosis Control Programme—
Conventional Chemotherapy Areas

IDENTITY CARD

Name: _____

Complete address: _____

_____

Sex: M ❑ F ❑ Age: _____ TB No: _____

Health Centre: _____

Disease Classification

❑ Pulmonary

❑ Extra-pulmonary

Site: _____

Treatment started on

___ ___ ___

Date Month Year

Type of Patient

❑ New ❑ Relapse

❑ Transfer in ❑ Other

❑ Treatment after default (specify) _____

Treatment

❑ Regimen 1

❑ Regimen 2

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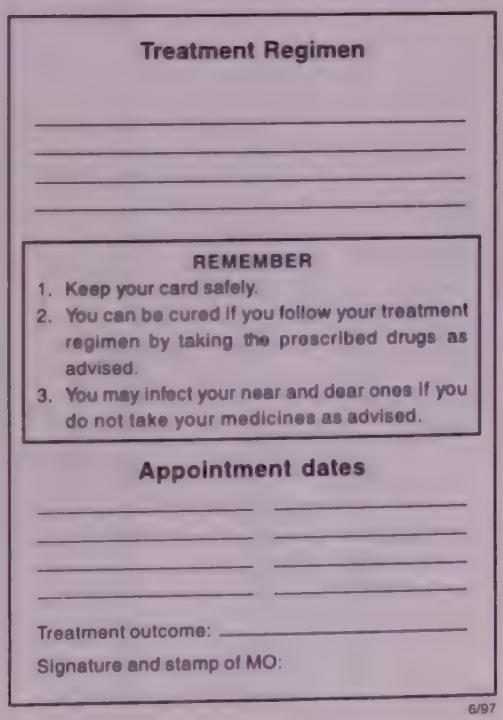

Treatment Regimen

_____

_____

_____

_____

REMEMBER

1. Keep your card safely.
2. You can be cured if you follow your treatment regimen by taking the prescribed drugs as advised.
3. You may infect your near and dear ones if you do not take your medicines as advised.

Appointment dates

_____ _____

_____ _____

_____ _____

_____ _____

Treatment outcome: _____

Signature and stamp of MO:

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NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS I

Treatment Card

State: _____ City/District: _____ Code district/subdistrict: _____

Name: _____ Patient TB No.: _____

Complete address: _____ Health Unit: _____

Sex: M ❑ F ❑ Age: _____

Name and address of Contact Person: _____

_____

Disease Classification

❑ Pulmonary

❑ Extra-pulmonary

Site: _____

I. INITIAL INTENSIVE PHASE—Prescribed regimen and dosages:

Tick (✓) the appropriate Regimen below.

❑ Regimen 1 [2HSE 10HE **or** 2HST 10HT]

❑ Regimen 2 [12HE **or** 12HT]

H: Isoniazid E: Ethambutol S: Streptomycin T: Thiacetazone

Type of Patient

❑ New ❑ Relapse

❑ Transfer in ❑ Failure

❑ Treatment after default ❑ Other (specify) _____

Month	Date	Lab No.	Smear result	Weight
0				
2				
6				
12				

Write C on date when the drugs were collected by the patient and draw a horizontal line (C——) to indicate the period for which medications were supplied for self-administration.

Month / Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

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II. CONTINUATION PHASE

(see Guidelines)

II

☐ Regimen 1 [2HSE 10HE **or** 2HST 10HT]

☐ Regimen 2 [12HE **or** 12HT]

Write C on date when the drugs were collected by the patient and draw a horizontal line (C ——) to indicate the period for which medications were supplied for self-administration.

Month / Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Remarks:

_____

_____

_____

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NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

Mycobacteriology Culture/Sensitivity Test Form

(1) Name of referring Unit: _____ Name of Laboratory: _____

Send results to (address): _____

_____

Months of treatment taken: _____

Name of patient: _____ Patient's TB No.: _____

(PLEASE TICK)

(2) ☐ Regimen 1 [2HSE 10HE **or** 2HST 10HT]

☐ Regimen 2 [12HE **or** 12HT]

☐ Other regimen (specify): _____

TREATMENT GIVEN	From date	To date
(H) Isoniazid		
(R) Rifampicin		
(Z) Pyrazinamide		
(E) Ethambutol		
(S) Streptomycin		
Other		

Date: _____ Medical Officer's name: _____

Prior sensitivity results and dates if known: _____

---

(3) Source of specimen if not sputum (specify): _____

Date of collection

				1	9		
d	d	m	m				

---

(4) **FOR LAB USE ONLY** Lab Serial No.: _____

Smear ☐ Positive (Grade: ☐ 3+ ☐ 2+ ☐ 1+ ☐ Scanty)

☐ Negative

Culture ☐ Positive ☐ Negative ☐ Contaminated ☐ Other

---

(5) **SENSITIVITY TESTS**

Drug	Sensitive	Resistant
(H) Isoniazid		
(R) Rifampicin		
(Z) Pyrazinamide		
(E) Ethambutol		
(S) Streptomycin		

Comments

Date: _____ Signature: _____

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NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

Transfer Form

(Fill in triplicate with carbon paper between the sheets. Send one copy to the Unit where the patient is referred, give one copy to the patient and retain one copy for records.)

Name of Transferring Unit: _____

Name of Unit to which patient is transferred (if known): _____

Name of patient: _____ Age: _____ Sex: M ☐ F ☐

Complete address: _____

_____

TB No.: _____ Date of starting treatment: _____

Disease Classification

☐ Pulmonary

☐ Extra-pulmonary

Site: _____

Treatment

☐ Regimen 1 [2HSE 10HE **or** 2HST 10HT]

☐ Regimen 2 [12HE **or** 12HT]

Type of Patient

☐ New ☐ Relapse

☐ Transfer in ☐ Treatment after default

☐ Other (specify) _____

Most Recent Sputum Status

Date _____ Month _____ Year _____

☐ Positive ☐ Negative

Drugs the patient is receiving: _____

Remarks: _____

_____ Signature: _____

Date transferred _____ Designation: _____

For use by the TB Unit where the patient has been transferred.

Name of patient: _____ TB No.: _____

Age: _____ Sex: M ☐ F ☐ Date of transfer: _____

Name of TB Unit: _____ Area: _____

The above-named reported at this TB Unit on: _____

Signature: _____ Designation: _____ Date: _____

(Send this part back to the Transferring Unit as soon as the patient has reported and has been registered.)

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NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Laboratory Register

Year _____

Lab Serial No.	Date	Name (in full)	Sex M / F	Age	Complete address (for new patients)	Name of Referring Health Centre	Reason for Examination*		Results			Signature	Remarks
							Diagnosis	Follow-up	1	2	3		

* If sputum is for diagnosis, put a tick (✓) mark in the space under "Diagnosis".
If sputum is for follow-up of patients on treatment, write the patient's TB No. in the space under "Follow-up".

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NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

I

Tuberculosis Register

TB No.	Date of registration	Name (in full)	Sex M / F	Age	Complete address	Name of Treatment Centre	Date of starting treatment	Regimen*	Disease class Pulm./ xpulm. (P/EP)	Type of Patient						
										New case (N)	Relapse (R)	Trans-fer in (T)	Failure (F)	Treat-ment after default (D)	Other (O)	

* Regimen 1 [2HSE 10HE **or** 2HST 10HT]
Regimen 2 [12HE **or** 12HT]

SUMMARY							
New smear-positive		Relapse		Smear-negative		Extra-pulmonary	
M	F	M	F	M	F	M	F

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NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

II

Tuberculosis Register

	Sputum examination								Date when treatment was stopped						Remarks
	Pretreatment 0 months		End of I.P.* 2 months		In C.P.** 6 months		End of treatment 12 months		Cured	Treatment completed	Died	Failure	Defaulted	Transferred out	
	Smear	Lab No.	Smear	Lab No.	Smear	Lab No.	Smear	Lab No.							

* I.P. Intensive Phase
** C.P. Continuation Phase

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Definitions

CLASSIFICATION OF TUBERCULOSIS CASES

Classification of pulmonary cases should be based on 3 sputum smear examinations. Sputum should also be examined for cases of suspected extra-pulmonary TB if pulmonary symptoms are present.

Pulmonary tuberculosis, smear-positive. TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB,

Or: Tuberculosis in a patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating Medical Officer,

Or: Tuberculosis in a patient with one sputum specimen positive for AFB and culture positive for *M. tuberculosis*.

Pulmonary tuberculosis, smear-negative. TB in a patient with symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by a Medical Officer, followed by a decision to treat the patient with a full course of anti-tuberculosis therapy,

Or: Diagnosis based on positive culture but negative AFB sputum examinations.

Extra-pulmonary tuberculosis. TB of organs other than the lungs, such as the pleura (TB pleurisy), peripheral lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis, tuberculoma of the brain, etc. Diagnosis should be based on one culture-positive specimen from an extra-pulmonary site, or histological evidence, or strong clinical evidence consistent with active extra-pulmonary TB followed by a Medical Officer's decision to treat the patient with a full course of anti-tuberculosis therapy.

Pleurisy is classified as extra-pulmonary TB.

A patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as a case of pulmonary TB.

TYPES OF CASES

New case. A patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month.

Relapse. A patient declared cured of TB by a physician, but who reports back to the health service and is found to be bacteriologically positive.

Transfer in. A patient who has been received into a Tuberculosis Unit/District, after starting treatment in another unit where he has been recorded.

Treatment after default. A patient who received anti-tuberculosis treatment for one month or more from any source and who returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more.

Failure case. A smear-positive patient who is smear-positive at 6 months or more after starting treatment. Failure also includes a patient who was initially smear-negative but who becomes smear positive during treatment.

Chronic case. A patient who remains smear-positive after completing a retreatment regimen.

"Other" case. Patients who do not fit into the above-mentioned categories. Reasons for putting a patient in this category must be specified.

TREATMENT OUTCOMES

Cured. An initially smear-positive patient who has completed treatment *and* had negative sputum smear results, on at least two occasions, one of which was at completion of treatment.

Treatment completed. Sputum smear-positive case who has completed treatment, with negative smears at the end of the initial phase but none at the end of treatment.

Or: Sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

Or: Extra-pulmonary TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

Died. Patient who died during treatment, regardless of cause.

Failure. A smear-positive case who is smear-positive at 6 months or more after starting treatment. Also, a patient who was initially smear-negative but who became smear-positive during treatment.

Defaulted. A patient who, at any time after registration, has not taken anti-TB drugs for 2 months or more consecutively.

Transferred out. A patient who has been transferred to another Tuberculosis Unit/District and his/her treatment results are not known.

NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

Quarterly Report on New and Retreatment Cases of Tuberculosis

Patients registered during _____ quarter* of 19____

Name of area _____ No.#_____

Name of Reporter:_____

Signature:_____

Date of completion of this form

				1	9		
d	d	m	m				

Block 1: All patients registered in the quarter

Pulmonary tuberculosis							Extra-pulmonary tuberculosis (4)		Total (5)		
Smear-positive					Smear-negative (3)						
New cases (1)			Relapses (2)								
M	F	Total	M	F	M	F	M	F	M	F	Total

Block 2: Smear-positive new cases only: from Column (1) above

Age-group (years)														Total		
0–14		15–24		25–34		35–44		45–54		55–64		65 and above				
M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Total

Block 3: Treatment regimen given

Type of patient	Regimen 1[a]		Regimen 2[b]		Total
	smear-positive	others	smear-positive	others	
New					
Relapse					
Failure					
Return after default					
Others					
Total					

Notes: * Quarters: 1st quarter January, February, March
2nd quarter April, May, June
3rd quarter July, August, September
4th quarter October, November, December

Number Identification number of the area

[a] Regimen 1 [2HSE 10HE **or** 2HST 10HT]
[b] Regimen 2 [12HE **or** 12HT]

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How to fill in the form

Block 1: New cases and relapses of tuberculosis registered during _____quarter of (year)_____ (*Fill in the quarter and the year.*)

Column (1):	Smear-positive new cases		Patients with sputum smear-positive pulmonary tuberculosis who have never received anti-tuberculosis treatment or have received treatment for less than 4 weeks.
Column (2):	Smear-positive relapses		Patients with sputum smear-positive pulmonary tuberculosis who were declared cured by a Medical Officer but have now got the disease again.
Column (3):	Smear-negative cases		Patients with pulmonary tuberculosis with 3 sputum samples negative for AFB, in whom the diagnosis of tuberculosis was made by means other than sputum microscopy.
Column (4):	Extra-pulmonary tuberculosis		Patients with tuberculosis of organs other than the lungs.
Column (5):	Total	Males	Add all male patients in columns 1+2+3+4
		Females	Add all female patients in columns 1+2+3+4
		Total	Add all patients (males+females) in columns 1+2+3+4

Block 2: Smear-positive new cases: from Column (1) above.

In this block enter the patients already recorded in Block 1, Column (1) according to their sex and age group. If the exact age of a patient is not known at the time of his/her registration it should be estimated to the nearest 5 years (e.g. 15, 20, 25, etc.).

Block 3: This gives regimen-wise break up of treatment regimens for all patients begun on treatment.

NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

Quarterly Report of Sputum Conversion of New Cases

Patients registered during _____ quarter of 19_____	Name of area: _____ No._____

Name of Reporter: _____ Signature: _____

Date of completion of this form:

				1	9		
d	d	m	m				

Complete this proforma for sputum smear-positive patients. The total number should be the same as in the Quarterly Report on New and Retreatment Cases of Tuberculosis.

Total number of new sputum-positive patients treated with Regimen 1	Sputum at 2 months		
	Negative	Positive	N.A.

Total number of new sputum-positive patients treated with Regimen 2	Sputum at 2 months		
	Negative	Positive	N.A.

N.A. – Not available; sputum examination was not done.

6/97

NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

Quarterly Report on the Results of Treatment of Tuberculosis Patients Registered 15–18 Months Earlier

Name of area:_____ No: _____ Date of completion of this form _____ 19 ____	Patients registered during _____ quarter of 19 ____	Name of Reporter*: _____ Signature: _____

Patients reported during quarter**	Type of patient (all smear-positive patients put on treatment)	Cured (1)	Treatment completed (2)	Died (3)	Failure (4)	Defaulted (5)	Transferred to another district (6)	Total number evaluated (sum of columns 1 to 6)
	Pulmonary smear-positive cases treated with Regimen 1							
	Pulmonary smear-positive cases treated with Regimen 2							

* The Reporter is the Medical Officer responsible, not the person completing this form. This form includes all smear-positive patients. These totals should match those of the Quarterly Report on New and Retreatment cases for the quarter.

* Of these, _____ (number) were excluded from evaluation of chemotherapy for the following reasons:

NATIONAL TUBERCULOSIS CONTROL PROGRAMME—CONVENTIONAL CHEMOTHERAPY AREAS

Quarterly Report on Programme Management and Logistics

District Level

Name of the District:_____ Quarter: _____ Year: _____

Microscopy Activities

Number of chest symptomatic **patients** whose sputum was examined for case-finding (diagnosis)	
Number of smear-positive **patients** diagnosed	

Staff Position and Training
(Check ✓ if in place or not during quarter)

District Tuberculosis Officer in place ❑ Yes ❑ No Trained in revised reporting formats ❑ Yes ❑ No

Medical Officer of the DTC ❑ Yes (No.___) ❑ No Trained in revised reporting formats ❑ Yes ❑ No

Statistical Assistant in place ❑ Yes ❑ No Trained in revised reporting formats ❑ Yes ❑ No

Treatment Organizer in place ❑ Yes ❑ No Trained in revised reporting formats ❑ Yes ❑ No

Laboratory Technician in place ❑ Yes ❑ No Trained in revised reporting formats ❑ Yes ❑ No

Equipment in place

Item	Number	In working condition	Not in working condition
Monocular microscopes			
Binocular microscopes			
X-ray machine			
Photocopier			
Overhead projector			
Jeep			
Two-/three-wheeler			

Medication

Item	Stock on first day of quarter	Stock received during quarter	Consumption during quarter	Stock on last day of quarter
Isoniazid 300 mg				
Isoniazid 100 mg				
Isoniazid 75 mg/ Thiacetazone 37.5 mg				
Isoniazid 150 mg/ Thiacetazone 75 mg				
Isoniazid 300 mg/ Thiacetazone 150 mg				
Ethambutol 800 mg				
Ethambutol 400 mg				
Ethambutol 200 mg				
Streptomycin 1000 mg				
Streptomycin 750 mg				
X-ray rolls				

Name of officer reporting (in Capital Letters): _____

Signature: _____

Date: _____

Quarterly Report on Programme Management

State Level

Name of State: _____ Quarter: _____

Year: _____

Number of Districts in the State: _____

Number of Conventional Chemotherapy Districts in the State: _____

The following reports are included (check ✓ to indicate that report is included)

- ☐ Quarterly Report on Case-Finding (number of Conventional Chemotherapy Districts reporting*: ____)
- ☐ Quarterly Report on Sputum Conversion (number of Conventional Chemotherapy Districts reporting*: _____)
- ☐ Quarterly Report on Treatment Outcomes (number of Conventional Chemotherapy Districts reporting*: _____)
- ☐ Quarterly Report on Programme Management (number of Conventional Chemotherapy Districts reporting*: _____)

* If any Conventional Chemotherapy district did not submit all reports, list names of District(s) and report(s) missing:

_____

Supervisory Activities by the State

Number of Conventional Chemotherapy Districts	Number of Conventional Chemotherapy Districts visited during quarter	Name of Conventional Chemotherapy Districts not visited (if any) and reason

Microscopy Activities (all Conventional Chemotherapy Districts combined)

Number of chest symptomatic **patients** whose sputum was examined for case-finding (diagnosis)	
Number of smear-positive **patients** diagnosed	

Laboratory Quality Control Network

Initial reading	State level reading		Percentage of discordance
	Number of positives	Number of negatives	
Number of positive slides checked: ____	(a)	(b)	(b/[a+b])
Number of negative slides checked: ____	(c)	(d)	(c/[c+d])

Staff Position and Training during quarter

Full-time State Tuberculosis Officer in place	❑ Yes ❑ No	Trained in revised reporting formats	❑ Yes ❑ No
Medical Officer State Headquarter in place	❑ Yes ❑ No	Trained in revised reporting formats	❑ Yes ❑ No
Full-time Director, STDC	❑ Yes ❑ No	Trained in revised reporting formats	❑ Yes ❑ No
Medical Officer, STDC	❑ Yes (No.___) ❑ No	Trained in revised reporting formats	❑ Yes ❑ No

Category of staff (all Districts combined)	Sanctioned	In place	Total trained in revised reporting formats
District Tuberculosis Officers			
Medical Officers of the DTC			
Laboratory Technicians/ Microscopists of the DTC			
Treatment Organizers of the DTC			
Statistical Assistants of the DTC			

Equipment at State Headquarter and STDC

Item	Number	In working condition	Not in working condition
Binocular microscopes			
X-ray machine			
Culture facility			
Sensitivity testing facility			
Photocopier			
Computer			
Facsimile machine			
Typewriter			
Overhead projector			
Minibus			
Jeep			
Two-/three-wheeler			

Name of officer reporting (in Capital Letters): _____

Signature: _____ Date: _____